

K955844

SUMMARY OF
SAFETY AND EFFECTIVENESS
INFORMATION

JUL 26 1996

1. Submitter: Varian Oncology Systems
 3045 Hanover Street
 Palo Alto, CA 94304

 Contact: Charles H. Will, Manager
 Regulatory Compliance & Safety
 Phone: (415) 424-5036
 FAX: (415) 424-4830

 Prepared: December 20, 1995
2. Device Name: Applicators and Accessories for Varian VariSource
 Remote High Dose Rate Afterloader
3. Predicate Omnitron PulmoCath
 Device: K901615/F
 Cleared on November 27, 1992

 Omnitron GYN Applicator System
 K913908/B
 Cleared on March 6, 1992

 Applicators for Varian VariSource Remote High Dose
 Rate Afterloader
 K952913
 Cleared on November 22, 1995
4. Description: The applicators for the Varian VariSource Remote
 High Dose Rate Afterloader are part of a remote
 controlled radionuclide applicator system, including
 an electromechanical device to enable an operator
 to apply, by remote control, a radionuclide source of
 high activity to be placed at various internal or surface
 body locations for radiation brachytherapy. The
 shape and materials of the applicator determine
 where it will be located for treatment.
5. Intended Use: The Varian VariSource Remote High Dose Rate
 Afterloader system, including the applicators included
 in this notification, is a device intended to be used by

properly trained and licensed medical personnel to provide radiation brachytherapy with a high specific activity radioisotope source to reduce the exposure times required to achieve a prescribed dose. Remote operation of the Afterloader eliminates the necessity of exposing medical personnel to radiation during hand loading or hand placement of radioactive sources on or within the body of a patient. The radioactive source is iridium-192, encapsulated in the end of a wire stored in the Afterloader and mechanically driven from it to a precisely described position for a specified dwell time during treatment. Between treatments the wire is retracted into the Afterloader and the source resides in a tungsten-shielded safe to limit personnel exposures to an acceptable, safe level. The Afterloader contains a radiation detector which signals whenever the source is not in the safe.

6. Technological
Considerations:

The applicators for the Varian VariSource Remote High Dose Rate Afterloader are identical or equivalent to the predicate devices in materials. Where a certain predicate device applicator contains low density polyethylene, the equivalent Varian applicator also contains low density polyethylene. Where a certain predicate device applicator contains PTFE and stainless steel, the equivalent Varian applicator contains PTFE and stainless steel.